REMARKS

Claims 56-139, 146, and 148-157 are pending. Claims 56-139 and 152-157 are withdrawn. Claim 150 is rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Claims 146 and 148-151 are rejected for obviousness-type double patenting over claims 1-7 of U.S. Patent No. 6,844,011 (the "'011 Patent"). Claims 146 and 148-151 are also provisionally rejected for obviousness-type double patenting over claims 1-21 of copending U.S. Serial No. 11/795,540 (the "'540 Application"). The Office also requests an amendment to the specification to change the title and to update the status of the parent application, U.S. Serial No. 10/698,734. By this reply, Applicant amends the title and specification, cancels claims 56-139 and 152-157, and addresses each of the rejections.

Amendment to the Title

Applicant has amended the Title of the Invention, as requested by the Office.

Amendment to the Specification

As requested by the Office, Applicant has amended the Cross Reference to Related Applications section of the specification to update the status of the parent application, U.S. Serial No. 10/698,734. As amended, the specification states that U.S. Serial No. 10/698,734 is "now U.S. Patent No. 7,582,313."

Rejection under 35 U.S.C. § 112, second paragraph

The Office rejects claim 150, stating that "recitation of the 'further separating said at least

one Hox11(+),CD45(-) cell into a third cell population...'...is unclear" (Office Action, p. 3). Applicant has amended claim 150 to address this rejection, which should be withdrawn.

Obviousness-Type Double Patenting

The Office rejects claims 146 and 148-151 for obviousness-type double patenting over claims 1-7 of the '011 Patent, stating

> Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-7 of U.S. Patent No.6,844,011 recites an isolated cells [sic], wherein said cell is a nonlymphocytic cell. Since the office does not have a laboratory to test the reference isolated nonlymphocytic cell it is applicant's burden to show that the reference cell does not have the same structural and functional properties as recited in the claims.

(Office Action, p. 3.) Applicant respectfully traverses this rejection.

The Requirements for Obviousness-type Double Patenting

M.P.E.P. § 804(II)(B)(1) states that "the first question to be asked is - does any claim in the application define an invention that is merely an obvious variation of an invention claimed in a patent? If the answer is yes, then an 'obviousness-type' nonstatutory double patenting rejection may be appropriate." M.P.E.P. § 804(II)(B)(1) also states that:

> A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the non-obviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

The question of obviousness, in cases of double patenting, is addressed using the criteria

established under 35 U.S.C. § 103. A finding of obviousness under 35 U.S.C. § 103 is only proper if all of the claim limitations are taught or suggested in the cited patent or patents on which the rejection is based (*In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)). For obviousness-type double patenting rejections, the prior patent specification cannot be used as prior art; obviousness must be determined based solely on the claims of the reference patent (see *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970)). Furthermore, in *Vogel*, the Court of Customs and Patent Appeals, the predecessor to the Federal Circuit, held that if the rejected claim defines more than an obvious variation, it is patentably distinct (*Id* at 442). In *Vogel*, the C.C.P.A. described an "obvious variation" as an aspect of the claimed subject matter that can be modified based on knowledge in the prior art (i.e., the permeability range of the packaging material; *Id* at 442).

Finally, the case law is clear with respect to genus-species relationships: "[t]hat a claim in a second patent or patent application 'dominates' subject matter claimed in a first patent does not, by itself, give rise to double patenting" (*In re Kaplan*, 789 F.2d 1574, 229 USPQ 678 (Fed. Cir. 1986); the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness (*In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)); "[t]he fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious" (*In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992))).

Rejection of Claims 146 and 148-151 over Claims 1-7 of the '011 Patent

Present claims 146 and 148-151 recite an isolated cell that expresses Hox 11 and that lacks expression of CD45 (i.e., a Hox11+, CD45- cell). In contrast, the claims of the '011 patent recite cells having no such structural limitations. Claim 1 of the '011 Patent recites:

> A transplantable composition for use in humans comprising isolated cells or isloated [sic] tissue of a type *normally bearing an HLA class I surface antigen* that causes an immune response against the cell or tissue in a human recipient, wherein the antigen is masked to decrease said immune response, such that upon introduction of the composition into a human, lysis of said cell or tissue is prevented; wherein said class I antigen is masked by contacting said cell or tissue with an antibody lacking the Fc portion, which does not fix complement and, which is capable of forming a complex with said class I antigen on said cell or tissue.

(Emphasis added.) The only structural feature defining the cells of claims 1-7 of the '011 Patent is the expression of HLA class I surface antigen. Nowhere do the claims of the '011 Patent teach or suggest a Hox11+, CD45- cell. Thus, the Hox11+, CD45- cell of present claims 146 and 148-151 is distinct from the HLA class I-expressing cells of claims 1-7 of the '011 Patent.

Furthermore, claims 146 and 148-151 do not define a composition that is merely an obvious variation of the cell-containing composition of claims 1-7 of the '011 Patent. The Hox11+, CD45- cell recited in present claims 146 and 148-151 cannot be considered an obvious variant when claims 1-7 of the '011 Patent only describe HLA class I surface antigen-expressing cells and do not recite or suggest a cell that expresses Hox 11 and that lacks expression of CD45. Therefore, claims 146 and 148-151 do not read on and do not define merely an obvious variation of the cell-containing composition of claims 1-7 of the '011 Patent. Thus, the Hox11+, CD45- cell of claims 146 and 148-151 are distinct from, and non-obvious in view of, the cell-containing composition of claims 1-7 of the '011 Patent.

Finally, the Examiner has not met the burden of showing that the cell-containing composition of claims 1-7 of the '011 patent constitutes an obvious variation of the presently claimed Hox11+, CD45- cell. One skilled in the art would not be directed, based solely on claims 1-7 of the '011 Patent, to prepare the presently claimed cell in view of the lack of any teaching or suggestion in the claims of the '011 Patent to do so (see *In re Royka, supra*).

Moreover, claims 1-7 of the '011 Patent describe only HLA class I surface antigen-expressing cells. Even if the Hox11+, CD45- cell of present claims 146 and 148-151 also expresses HLA class I surface antigen, this alone would be insufficient to establish the obviousness of present claims 146 and 148-151 for double patenting purposes as it only establishes a genus-species relationship, which is insufficient by itself to establish a *prima facie* case of obviousness (*see In re Kaplan, supra*; *In re Baird, supra*; and *In re Jones, supra*). A cell having the characteristics of the cell of present claims 146 and 148-151 is not taught or suggested by claims 1-7 of the '011 Patent. Thus, nothing in claims 1-7 of the '011 Patent renders obvious the Hox11+, CD45- cell of present claims 146 and 148-151.

For all of the reasons provided above, Applicant respectfully requests that the rejection of claims 146 and 148-151 for obviousness-type double patenting over claims 1-7 of the '011 Patent be withdrawn.

Rejection of Claims 146 and 148-151 over Claims 1-21 of the '540 Application

Claims 146 and 148-151 are also provisionally rejected for obviousness-type double patenting over claims 1-21 of the '540 Application.

M.P.E.P. § 804(I) states:

> If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

The present application has an earlier filing date than the '540 Application. As Applicants have addressed all other bases of rejection, the double-patenting rejection should be withdrawn.

CONCLUSION

Applicant submits that the claims are in condition for allowance and such action is respectfully requested.

Enclosed is a petition to extend the period for replying for two months, to and including December 8, 2009, and authorization to deduct the fee required under 37 C.F.R. § 1.17(a) from Deposit Account No. 03-2095. If there are any other charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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